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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/599,113	09/20/2006	Eric Jonsen	US040147US	1777

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EXAMINER

BEHRINGER, LUTHER G

ART UNIT	PAPER NUMBER
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3766

MAIL DATE	DELIVERY MODE
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10/30/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/599,113	Applicant(s) JONSEN ET AL.	
	Examiner Luther G. Behringer	Art Unit 3766	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 04 August 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-7,9-16,18-21 and 23 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 9-16 is/are allowed.
- 6) ☒ Claim(s) 1-7,18-21 and 23 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 20 September 2006 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--------------------------------------------------------------------------------------|-------------------------------------------------------------------|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. This office action is in response to the communication received on 08/04/2009 concerning application no. 10/599113 filed on 09/20/2006.

Response to Arguments

2. Applicant's arguments with respect to claim(s) 1 – 7, 18 – 21 and 23 have been considered but are moot in view of the new ground(s) of rejection.

Claim Objections

3. Amendments to claim 1 have obviated the necessity of the objections raised in the action dated 05/04/2009. Therefore, those objections are withdrawn.

Claim Rejections - 35 USC § 102 / 103

4. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

5. Claim(s) 1 – 3, 6, 7, 18 – 20 and 23 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over **Heath (US 4,419,998)** (cited in a prior action).

With regard to **claim 1**, Heath discloses an electrode comprising: an electrode body having a first and second side, wherein the first side comprises a flexible, non-conductive moisture barrier layer, *foam base 67*, comprising a heat-sealable periphery and the second side comprises a conductive layer, **71**; an electrically conductive gel layer, **75**, disposed on the electrode body and which is further in electrical communication with the conductive layer, the periphery of the heat-sealable moisture

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barrier layer extending beyond the periphery of the gel layer; and a rigid non-conductive release liner, **83**, to which the flexible moisture barrier layer is heat-sealed around the periphery of said gel layer by a heat seal with the gel layer in contact with the release liner to form a vapor, air, and/or moisture-proof enclosure of the gel layer so that the electrode may be stored in a desiccation-retarding condition without the need for storing the electrode in a separate desiccation-retarding pouch or envelope (Fig. 4; Col. 15, ll. 9 – 18).

Applicant is reminded of the federal circuit decisions applied to product-by-process claims. "[E]ven though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." *In re Thorpe*, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985) In the instant case, specifying the sealing mechanism as a heat seal renders this claim a product-by-process claim.

6. Heath discloses the claimed invention except for a peel tab extending from a heat sealing release liner on the flexible non-conducting moisture barrier. It would have been obvious to one having ordinary skill in the art at the time of the invention to utilize heat sealing to achieve predictable results of providing a moisture proof barrier since the examiner takes **Official Notice** of the equivalence of an adhesive hermetic seal and a heat sealed moisture barrier for their use in the defibrillator electrode art and the

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selection of any of these known equivalents to prevent the desiccation of the electrolytic gel within the defibrillator electrode would be within the level of ordinary skill in the art.

7. Heath discloses the claimed invention except for the peel tab extending from the heat seal. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the electrodes as taught by Heat, with a peel tab extending from the heat seal since it was known in the art that peel tabs are used to improve the ease with which a seal is removed. In the instant case, the examiner is citing Craige, III et al. (US 2004/0260376; element **43** in Figs. 2, 3 – 3B; previously cited) as one example.

Regarding **claim 2**, Heath discloses wherein the heat-sealable material comprises a thermoplastic polymeric material, *thin, rigid, transparent plastic* (Col. 15, ll. 9 – 18).

With regard to **claim(s) 3 and 20**, Heath discloses wherein the flexible barrier layer further comprises a vapor or air barrier material comprising a polymeric film or sheet, a foil material, or a coated substrate comprising a metal, textile, paper, or non-woven material coated with a polymeric material, *plastic* (Col. 15, ll. 9 – 18).

Regarding **claim(s) 6 and 19**, Heath discloses wherein the conductive layer comprises a metal sheet or foil, a conductive ink, or a laminate comprising a metal component disposed over a polymeric substrate (Col. 6, ll. 20 – 25).

With regard to **claim(s) 7 and 23**, Heath discloses wherein the electrode further comprises a lead wire, **43**, that is connected to the flexible barrier layer of the electrode and which electrically connects the electrode to a medical device (Figs. 2 & 4).

Regarding **claim 18**, Heath discloses all of the limitations of claim 18 as disclosed in claim 1 and in addition discloses a lead wire, **41 or 43** *coupled to a second electrode via connector 333*, electrically coupled to each electrode body by means of a path that does not disrupt the moisture integrity of the release liner seal (Figs. 2 and 4).

8. Claim(s) 4, 5 and 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over **Heath (US 4,419,998)** in view of **Keusch et al. (US 4,989,607, herein Keusch)** (cited in a prior action).

With regard to **claim 4**, Heath fails to disclose wherein the flexible barrier layer further comprises a vapor or air barrier material comprising a fluoropolymer film.

However, Keusch teaches wherein the flexible barrier layer further comprises a vapor or air barrier material comprising a fluoropolymer film (Col. 13, ll. 46 – 49).

9. A person of ordinary skill in the art, upon reading the reference, would have recognized the desirability of using a material to create a vapor or air barrier to achieve sterility. Thus, it would have been obvious to a person having ordinary skill in the art at the time of the invention to modify Heath to include the vapor or air barrier as taught by Keusch, since maintaining a sterile medical device aids in the prevention of transmission of disease.

10. Keusch discloses the claimed invention except for the fluoropolymer film. It would have been obvious to one having ordinary skill in the art at the time the invention was made to use a fluoropolymer, since it has been held to be within the general skill of a

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worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. *In re Leshin*, 125 USPQ 416.

Regarding **claim(s) 5 and 21**, Heath in view of Keusch discloses wherein the flexible barrier layer comprises a laminate comprising a first layer of a heat-sealable layer comprising polyethylene disposed over a second layer of a vapor barrier comprising a fluoropolymer film (Keusch: Col. 13, ll. 46 – 49).

Allowable Subject Matter

11. Claim(s) 9 – 16 are allowed.

12. The following is a statement of reasons for the indication of allowable subject matter: Walters (US 5,916,244), Keusch et al. (US 4,989,607), Heath (US 4,419,998) Olson et al. (US 5,817,151), and Shepard (US 3,556,105) all fail to disclose, solely or in combination, the following patentable limitations:

- Disposing a pair of electrodes on the opposite sides of a rigid release liner
- Embedding a conductive path within the rigid release liner to allow continuity testing of stored electrodes

Conclusion

13. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Luther G. Behringer whose telephone number is (571)270-3868. The examiner can normally be reached on Mon - Thurs 9:00 - 6:30; 2nd Friday 9:00 - 5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Carl Layno can be reached on (571) 272-4949. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Carl H. Layno/
Supervisory Patent Examiner, Art Unit 3766

/Luther G Behringer/
Examiner, Art Unit 3766